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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,917	01/24/2001	Alain P. Vicari	SF0896K	5028

24265 7590 07/28/2005

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,917	VICARI ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-24,27,29,31,33,35,36 and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24, 27, 29, 31, 33, 35-36, and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/05 has been entered. As requested, applicant's amendment and arguments filed on 4/26/05 have been entered. Claims 21-24, 27, 29, 31, 33, 35-36, and 69 are currently pending and under examination in instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 103

The rejection of claims 21-24, 27, 29, 31, 33, 35-36, and 69 under 35 U.S.C. 103(a) as being unpatentable over EP 0 974 357 A1 (7/16/98), hereafter referred to as Caux et al., in view of WO 98/14573 (4/9/98), hereafter referred to as Luster et al., and Dieu-Nosjean et al. (1999) J. Leuk. Biol. Vol. 66, 252-262, is withdrawn in view of applicant's amendment to claim 21 which now recites the sequential administration of a protein chemokine and a nucleic acid encoding an antigen, wherein said chemokine is MCP-4. The scope of the claims as amended is now

commensurate in scope with the evidence of "unexpected results" provided by the Declaration under 37 CFR 1.132 by Dr. Vicari. As noted in previous office actions, the declaratory evidence demonstrates that the injection of hMCP-4 protein prior to the administration of nucleic acid encoding an antigen increases antigen specific IgG antibody generation, whereas prior injection of hMIP-3α does not. As such, the office accepts the declaratory data provided as evidence that the increased antibody levels observed with MCP-4 protein would not have been expected based on the results obtained using MIP-3α protein, since neither Luster et al. nor Dieu-Nosjean et al. teach or suggest that the administration of MCP-4 protein increases antigen-specific humoral responses. Therefore, the rejection of record has been withdrawn.

The following new grounds of rejection apply to the claims, therefore this action is non-final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-24, 27, 29, 31, 33, 35-36, and 69 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendment necessitated this new grounds of rejection.

The applicant has amended claim 21, adding the limitation that the method comprises, "sequentially administering a protein chemokine and a nucleic acid encoding an antigen". However, the claim also contains the limitation, "wherein said antigen and said chemokine are not physically linked as a fusion protein". This limitation conflicts with the limitation added by amendment for sequential administration of a protein chemokine and a nucleic acid encoding an antigen. Since the antigen is not in protein form, but rather is encoded by the nucleic acid, it is unclear how the negative limitation that the antigen and chemokine are not physically linked as a fusion protein applies. As such, the claim as written is confusing and the metes and bounds of the claim cannot be determined.

Note that claims 22-24, 27, 29, 31, 33, 35-36, and 69 all depend on claim 21 and thus are indefinite as well for the same reasons.

Claim 36 is further indefinite. Claim 36, an original claim which depends on claim 21, recites the limitation wherein the chemokine is administered in the form of a vector. Since claim 21, as amended, now recites that a protein chemokine is administered, the limitation of claim 36 conflicts with the limitations of claim 21. As such, the metes and bounds of the claim cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-24, 27, 29, 31, 33, 35-36, and 69 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant claims recite methods of using a "biologically active fraction of MCP-4". The specification does not provide sufficient written description of a "biologically active fraction of MCP-4". It is first noted that the specification does not refer to or discuss a "fraction" of MCP-4. The specification provides a general statement that "biologically active **fragments**" of MCP-4 can be used in the instant methods. Since a "fraction of MCP-4" is not defined or disclosed in the specification, it is unclear whether a "fraction of MCP-4" is the same as or related to a "fragment of MCP-4". Further, the specification provides not specific description for any biologically active "fragment" or "fraction" of MCP-4. The specification only provides description for the full length MCP-4 polypeptide.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is claimed." (See page 1117). The instant specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American*

Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may also be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). The applicant has not provided any description or reduction to practice of a single biologically active “fragment” or “fraction” of MCP-4. The specification further does not provide any description of the structures of domains present in the full length MCP-4 responsible for its biological activity such that a biologically active fragment could be identified. It is also noted that the specification’s working examples are all directed to the use of full length MCP-4. Based on the applicant’s specification, the skilled artisan cannot envision the detailed chemical structure of the polypeptide sequences which comprise a biologically active “fragment” or “fraction” of MCP-4. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. See *Fiers v. Revel,* 25 USPQ2d 1602 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016. Thus, for the reasons outlined above, “biologically active fractions of MCP-4” are not adequately described by the specification as filed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER